

INSTRUCTIONS FOR COMPLETING THE 340B REGISTRATION FORM

(for use by Black Lung Clinics, Consolidated Health Center Programs, Federally Qualified Health Center Look-alikes, FQHC638, Comprehensive Hemophilia Treatment Centers, Native Hawaiian Health Care Programs, Ryan White Programs, and Urban Indian Programs)

While an organization may be eligible to participate in the 340B Program by virtue of its status (i.e., receiving a grant from an eligible program), it must notify the Office of Pharmacy Affairs (OPA) of its intention to participate by completing and submitting a signed original of the "340B Program Registration Form for Covered Entities." Once the OPA receives, verifies, and processes this information, the entity will be eligible to purchase pharmaceuticals at the 340B price beginning the next calendar quarter. If your organization has been awarded a grant recently, you may want to include a copy of your Notice of Grant Award to expedite the processing of your form.

In order to allow sufficient time for verification and processing of the information on the registration form, the quarterly deadlines for submission of registration forms to OPA are:

December 1 to become effective as a participating covered entity for the quarter beginning January 1;
March 1 to become effective as a participating covered entity for the quarter beginning April 1;
June 1 to become effective as a participating covered entity for the quarter beginning July 1; and
September 1 to become effective as a participating covered entity for the quarter beginning October 1.

If your submission is close to the deadline, you are advised to FAX the form to OPA and mail the original.

NOTE ON SIGNATURES – the Registration Form must be signed by a responsible representative of the covered entity. The responsible representative may be the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Program Director. Forms that are signed by an individual that OPA determines is not an acceptable representative will not be processed. If you are in doubt regarding the acceptability of a signature, please contact OPA prior to submission of your registration form. Please include the title, telephone number, and e-mail address of the individual who is signing.

NOTE ON SHIPPING ADDRESSES – complete this section ONLY if your pharmaceuticals will be shipped to an address that is different from the covered entity address. However, do NOT use this section to provide information for a contracted pharmacy arrangement. Use the form found at this [link](#) for contracted pharmacy information.

The registration process is not complete unless the registration form has been completed in its entirety (all requested information is filled in on the form) and the original, signed copy is received by OPA. Accurate information on the entity should always be reflected on the OPA website. It is the covered entity's responsibility to notify OPA of any changes in writing.

Once your form has been processed, the OPA will notify you (at the e-mail address that you provide on the Program Registration Form) of your effective date in the 340B Program and provide you with your 340B identification number, a unique number that OPA assigns to each covered entity. Please use this number in all correspondence to OPA. This is the number used by manufacturers, wholesalers, and others to search the OPA database to verify your participation in the 340B program. It is the entity's responsibility to tell its wholesaler or manufacturer that it is registered for 340B prices when it places an order. You may view the information for your entity on the [OPA website](#) by entering the 340B ID number in the field labeled "340B ID." New additions to the database are closed two weeks prior to the start of the quarter. **If you do not see your entity listed on the database, you are NOT registered.**

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-XXXX. Public burden is estimated to average XX minutes per respondent, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14-33, Rockville, Maryland 20857.

To complete the registration process, an original, signed form must be submitted to and received by: Office of Pharmacy Affairs, 5600 Fishers Lane, Mail Stop 10C-03, Rockville, MD 20857

OFFICE OF PHARMACY AFFAIRS

340B PROGRAM REGISTRATION FORM FOR COVERED ENTITIES

Acknowledgement of Covered Entity Participation in Outpatient Discount Drug Pricing under Section 340B of the Public Health Service Act, as amended by Section 602 of the Veterans Health Care Act of 1992

I. Covered Entity Name: _____
Street Address: _____

City, State, ZIP _____

Billing Address (if different): _____

City, State, ZIP _____

Shipping Address (if different): _____

City, State, ZIP _____

Entity Type: (see next page for list of codes) _____

UDS or Grant Number (if known/applicable): _____

II. Medicaid Billing Information - You **must** answer the following question regarding Medicaid billing.

Will you bill Medicaid for drugs purchased at 340B Drug Prices? **Yes** **No**

If **"Yes"**, your Pharmacy/Clinic Medicaid Provider Number(s) and/or National Provider Identifier(s) (NPI) is required (please include the number(s) and State): _____

If you bill Medicaid for pharmaceuticals that may be subject to a payment of a Medicaid rebate to a state, you must submit to OPA the pharmacy Medicaid number and/or clinic Medicaid number and/or NPI which is used to bill Medicaid for outpatient drugs. If you are unsure of your pharmacy Medicaid number and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status in our database is accurate to prevent Medicaid rebates on drugs that were sold to a covered entity at a discounted price. If you bill at an all-inclusive rate, which includes pharmaceuticals, or if you do not bill Medicaid, state N/A (Not Applicable) which is entered in our database. You should notify OPA prior to any change in your Medicaid billing status. For more information, go to: <http://www.hrsa.gov/opa/medicaidexclusion.htm>

III. Signed Agreement:

The undersigned represents and confirms that he/she is fully authorized to bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The covered entity will comply with all of the requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines, including, but not limited to, the prohibitions on duplicate discounts/rebates, and drug diversion. The undersigned further acknowledges the 340B Covered Entity's responsibility to contact OPA if there is a change in regard to any of these criteria.

Name (please type/print) _____ Title _____ (e.g.: CEO, CFO, COO)

Signature _____ Date: _____

Telephone Number: _____ Ext. _____ Email Address: _____

Contact Name: _____ Title _____

Telephone Number: _____ Ext. _____ Fax Number: _____

Email Address: _____

List of Covered Entity Type Codes

Please select from the list below and enter the appropriate code(s) for your entity on the Registration Form under “Entity Type.” You should enter all codes for which your organization is eligible as the scope of your grant may determine the eligibility of pharmaceuticals purchased under 340B.

| <u>Code</u> | <u>Program</u> |
|--------------------|---|
| BL | Black Lung Clinics Program |
| CH | Consolidated Community Health Center Cluster Program (includes Community Health Centers, Migrant Health Centers, Healthcare for the Homeless Programs, Public Housing Primary Care Programs, and School-Based Health Center (Healthy Schools, Healthy Communities) Programs |
| FQHC638 | Tribal Contract/Compact with IHS (P.L. 93-638) |
| FQHCLA | Federally Qualified Health Center Lookalike NOTE: if your organization is an FQHCLA, you MUST notify OPA if you are successful in receiving a Section 330 grant at a later date. |
| HM | Comprehensive Hemophilia Treatment Center |
| HV | Ryan White Part C |
| NH | Native Hawaiian Health Care Program |
| RWI | Ryan White Part A |
| RWII | Ryan White Part B |
| RWIID | Ryan White ADAP Rebate Option |
| RWIIR | Ryan White ADAP Direct Purchase |
| RW4 | Ryan White Part D |
| SPNS | Special Projects of National Significance |
| UI | Urban Indian |

Disproportionate Share Hospitals (DSH) – go to this [link](#) for the appropriate forms.